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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
MIDDLE DIVISION

CIVIL ACTION NO.:

ROY D. CLEVELAND JR.,

Plaintiff,

v.

SMITH & NEPHEW, INC., a Tennessee Corporation,

Defendant.

COMPLAINT FOR DAMAGES

Plaintiff, Roy D. Cleveland Jr. states the following for his complaint and jury demand against Defendant, Smith & Nephew, Inc., a Tennessee Corporation:

JURISDICTION AND VENUE

1. Plaintiff Roy D. Cleveland Jr. is, and at all times relevant to this action was, a citizen and resident of the State of Alabama with his place of residence on Moon Road, Gadsden, Alabama, which lies in Etowah County.

2. Defendant, Smith & Nephew, Inc., is and at all times relevant to this action, was a resident and/or corporation with its principal place of residence and/or business in a state other than the State of Alabama.

3. Complete diversity of citizenship exists pursuant to 28 U.S.C. § 1332. At all times relevant to this cause of action, the Defendant had the requisite minimum contacts with the State

of Alabama, and the amount in controversy in this action exceeds Seventy Five Thousand Dollars ($75,000.00) exclusive of interest and costs.

4. The Northern District of Alabama also is the proper venue for this matter pursuant to 28 U.S.C. § 1391 because a substantial number of the events, acts and omissions forming the basis of Plaintiff's claims took place in the Northern District of Alabama, and because Defendant conducts substantial business in this District. Etowah County, where Plaintiff resides, is furthermore part of the District of the United States District Court for the Northern District of Alabama, Middle Division.

FACTUAL BACKGROUND

5. Defendant Smith & Nephew is a global medical technology company, with its headquarters in England, a presence in more than 90 countries worldwide, and total sales of $4.6 billion in 2014. Its domestic headquarters are in Memphis, Tenn.

6. Defendant markets, manufactures, and sells prosthetic hip devices for use in total hip arthroplasty and resurfacing arthroplasty, specifically the hip socket, acetabulum, and the ball, or femoral head. These hip replacement products include the Birmingham Hip Resurfacing System ("BHR"), which Smith & Nephew withdrew from the U.S. market and subsequently issued a Class II recall on September 10, 2015, due to high failure rates, especially for women.

7. In a resurfacing arthroplasty, the femoral head is not removed but is instead trimmed and capped (resurfaced) with a smooth metal covering. This procedure differs from a total hip replacement, which includes the placement of a prosthetic femoral stem.

8. The BHR device consists of a femoral head component and a hemispherical acetabular cup that is made in a range of 12 sizes. The cup fits into the patient's hip socket, or acetabulum, and then rubs against the femoral head during articulation (movement) of the patient's

hip joint. Both components are made of cobalt and chromium metal alloys, and thus are "metal-on-metal" hip implant components.

9. In order to sell the metal-on-metal BHR device in the United States, Defendant submitted an application for Pre-Market Approval ("PMA") to the U.S. Food and Drug Administration on or about July 19, 2004.

10. The U.S. Food and Drug Administration did not approve the application as submitted because the device's PMA was deficient for a number of reasons. The deficiencies in the PMA application forced Smith & Nephew to make as many as eighteen (18) amendments and changes to the application before it was approved. The exact reasons for these deficiencies, and the documents describing them, are solely within the possession of Smith & Nephew and/or the FDA, and can be described in greater detail only with the assistance of discovery in this proceeding.

11. Almost two years after the initial application, the FDA on May 9, 2006, finally granted conditional approval to Smith & Nephew to market the BHR based on strict guidelines that required ongoing clinical studies, monitoring, reporting of certain adverse events, post-marketing surveillance and other measures.[1]

12. Failure to follow the requirements of the conditional approval of the BHR constitutes a violation of the Federal Food, Drug, and Cosmetic Act ("Act"), pursuant to 21 CFR 801.19, and furthermore voids any legal protection that Defendant enjoys from tort claims as part of the device's PMA status. For example, Page 4 of the approval letter from the FDA states that

[1] *See* Center for Drug Evaluation and Research, Food and Drug Administration, *The Clinical Impact of Adverse Event Reporting*, MedWatch, October 1996; see also Division of Epidemiology, Office of Surveillance and Biometrics, Food and Drug Administration, *Approval Studies for Medical Devices Workshop*, June 2009, available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/PostApprovaStudies/UCM208562.pdf

"failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

13. As part of the PMA requirements, Defendant initiated a long-term safety and effectiveness study, based in part on the outcomes of the first 350 patients in the Overall McMinn Cohort in the United Kingdom, as well as individuals implanted with the BHR at locations across the United States.

14. As part of the Study, Defendant agreed to collect data from clinical exams, x-rays, and an annual questionnaire, and compile information on each patient's Harris Hip Score, including pain, function, movement, revision status and adverse events during a 10-year period following implantation. But at least one of the study surgeons, based in Florida, dropped out of the study, and others failed to notify patients of the health risks of metallosis, even after study subjects reported toxic levels of cobalt and chromium in their blood. The study results also were biased because men, who typically have a lower failure rate in a resurfacing procedure, made up approximately three-quarters of study participants, compared to women who made up only one quarter of participants.[2]

15. Despite the fact that the Study was a requirement of the PMA, Smith & Nephew prematurely terminated the Study in 2012 before the planned completion date, and thus did not comply with the terms of the PMA. At the time, the FDA reported the status of the BHR Study as "progress inadequate"[3] in part because patient enrollment milestones were not met, and because it failed to timely submit scheduled reports to the FDA pursuant to 21 CFR 814.84, *et. seq.* Further

[2] See, e.g., Tables 6-7, BHR System Post-Approval Study, 84-Month Interim Study Status Report, May 6, 2013.
[3] AccessData FDA, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm?start_search=S#S (last visited February 11, 2017).

evidence of PMA violations is contained in FDA correspondence to Smith & Nephew dated July 8, 2014, in which the agency issued a deficiency notice and warned the company about bias in its study results because Smith & Nephew had failed to reach the 80 percent target follow-up rate with study participants. Smith & Nephew did not even bother to respond to the FDA's query within the required time frame.[4]

16. Smith & Nephew also recalled numerous versions of the BHR device in 2007 due to labeling problems and other issues, and it submitted at least twenty-seven (27) proposed supplements to the terms of the PMA from the time of its initial approval in 2006 through May 2014.

17. Smith & Nephew also agreed to implement a training program as part of the PMA including quarterly teleconferences with surgeons during the first two years of the U.S. portion of the safety study, and Smith & Nephew agreed to provide the FDA with an analysis of adverse events and complaints related to the BHR system.

18. On June 4, 2015, Smith & Nephew announced the voluntary removal of the BHR device from the U.S. market due to unreasonably high failure rates for certain demographic groups, including all women, all men age 65 or older, and all men with requiring femoral head sizes 46 mm or smaller.[5]

19. The market withdrawal of the BHR followed numerous other warning signs, including an Urgent Field Safety Notice[6] sent to doctors in November 2014 about high revision

[4] Jeff Sprague, Regulatory Affairs, Smith & Nephew, Letter to FDA Center for Devices and Radiological Health, August 6, 2014 (requesting, in part, a two-week extension to respond).
[5] Smith & Nephew, *Statement Regarding BHR System*, June 4, 2015, available at http://www.smith-nephew.com/news-and-media/media-releases/news/statement-regarding-bhr-system/ (last visited February 11, 2017)(stating that "… Smith & Nephew considers that these patient groups may be at a greater risk of revision surgery than previously believed, and is therefore removing small sizes and updating the IFU to contraindicate the BHR for women.")
[6] Smith & Nephew, *Urgent Field Safety Notice*, FSCA R-2014-12.

rates for the same population groups mentioned above, and for patients with congenital dysplasia, and diagnosed avascular necrosis. But Smith & Nephew knew about these and other problems years before it finally issued a recall, and it continued to promote the BHR device even after well-documented problems with other metal-on-metal hips such as the Zimmer Durom, DePuy ASR, Biomet Magnum, DePuy Pinnacle and Wright Conserve, all of which were removed from the U.S. market earlier. To be certain, Smith & Nephew had numerous chances to follow the lead of its competitors and warn patients of the unreasonable failure rate associated the BHR device.[7] For example, a February 2012 article in the Journal of Bone and Joint Surgery revealed the BHR has a 26 percent failure rate in women after ten years, and the authors of the article warned that "results in women have been poor and we do not recommend metal-on-metal resurfacing in women."[8]

20. In addition to the above-mentioned market withdrawal, Smith & Nephew issued a Class 2 recall of the BHR device on September 10, 2015, covering more than 10,000 units of the device in the stream of commerce. The reason for the recall was described as "revision rates which were higher than established benchmarks" pursuant to 21 CFR §7.55.

21. Data published in connection with the recall show a total of 288 "device problems" with the BHR, including numerous safety problems related to "metal shedding debris" and other symptoms typical of metal-on-metal device failure.[9]

22. Data compiled by the National Joint Registry of England and Wales show the BHR 42 mm femoral head component has a seven-year revision rate of 11.76 percent, well above the

[7] In its 2012 post-marketing annual report to the FDA, Smith & Nephew disclosed 356 reportable complaints for the BHR alone between March 1, 2011, and February 29, 2012. The following year, it disclosed 380 reportable complaints between April 1, 2012, and April 1, 2013.
[8] D.W. Murray, et. al., The Ten-Year Survival of the Birmingham Hip Resurfacing, J. Bone & Joint Surg., 2012;94-B.
[9] Many of the failures have been reported to Smith & Nephew in the last 18 months, suggesting that additional failure reports due to metallosis will continue in the future. A list of the device failures is available through the FDA's Manufacturer and User Device Experience, or MAUDE, database, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=NXT (last visited Feb. 11, 2017).

normal acceptable failure rate for a device of this type.

23. A separate study of the BHR device in England showed that out of 319 patients, nearly 30 percent had modified Harris Hip Scores below 90 at their ten-year follow up exam, and approximately 12 percent of patients had scores below 80.[10] A score above 90 is considered excellent. Scores below that number are described as either poor, fair, or good.

24. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, Defendant's BHR resurfacing products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and sometimes irreversible injuries, conditions, and damage to a significant number of patients, including Plaintiff.

25. In addition to the high failure rate of the BHR device, and the Class II recall, Defendant Smith & Nephew also failed to comply with numerous requirements of the PMA, including the safety study, surgeon teleconferences, and adverse event reporting, all of which are described in more detail below.

26. Defendant consistently under-reported and withheld information about the likelihood of the BHR to fail and cause injury and complications, and Defendant has misrepresented the efficacy and safety of the BHR resurfacing products, actively misleading the medical community, patients, and the public at large.

27. Defendant knew, and continues to know, that its disclosures to the public and Plaintiff were and are incomplete and misleading; and that Defendant's BHR resurfacing products were and are causing numerous patients severe injuries and complications. Defendant suppressed

[10] FDA Medical Devices, *Post-Approval Studies, PMA P040033*, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm?t_id=340223&c_id=189#tt (last visited Feb. 11, 2017).

this information, and failed to accurately and completely disseminate or share this and other critical information with the medical community, health care providers, and patients.

28. As a result, Defendant actively and intentionally misled and continues to mislead the public, including the medical community, health care providers, and patients, into believing that the Defendant's BHR resurfacing products were and are safe and effective, leading to the prescription for and implantation of the BHR resurfacing products into patients such as Plaintiff. For example, in its 2015 annual report to the FDA, Smith & Nephew still did not list female patients or smaller bearing sizes in its list of contraindications for the BHR system, even though numerous studies cited those patient groups as being particularly at risk of premature failure.[11]

29. Defendant failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of Defendant's BHR resurfacing products.

30. As compared to Defendant's BHR resurfacing products, feasible and suitable alternative designs, procedures, and instruments for implantation and treatment of damaged and worn parts of the hip joint and similar other conditions have existed at all times relevant.

31. Defendant's BHR resurfacing products were at all times utilized and implanted in a manner foreseeable to Defendant.

32. Defendant provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing Defendant's BHR resurfacing products, thereby increasing the sales of the BHR resurfacing products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

[11] Jeff Sprague, Regulatory Affairs Specialist, PMA Annual Report to FDA, May 2, 2015.

PRE-EMPTION AND THE FEDERAL FOOD, DRUG AND COSMETIC ACT

33. Manufacturers of the Class III devices such as the BHR are required to obtain premarket approval ("PMA") from the Food and Drug Administration before they can make their products available to patients. 21 U.S.C. § 360(e). The PMA process is part of the regulatory framework of the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1976.

34. The MDA imposes a number of ongoing requirements, including requiring manufacturers to strictly adhere to the design, manufacturing, packaging, storage, labeling, distribution, and advertising specifications in the PMA approval order pursuant to 21 C.F.R. § 814.80, and to conduct ongoing safety studies and notify the FDA of any unexpected serious problems with the device.

35. The MDA contains an express preemption provision found at 21 U.S.C. § 360k, so long as the manufacturer follows all of the conditions set forth in the PMA and in the MDA generally.

36. The MDA does not, however, preempt state law claims that are sufficiently parallel to a violation of the above federal requirements, so long as those claims are based on violations of state law duties that predate and operate independently from the federal requirements.

37. Hundreds of patients across the United States have sought compensation from Smith & Nephew due to premature failure of the BHR device, based on violations of state common law duties and the federal requirements. On information and belief, more than 350 plaintiffs have brought BHR claims against Smith & Nephew in Shelby County, Tenn., state court. Other claims have been filed and/or removed to U.S. District Courts in Arizona, California, Colorado, Florida, Kentucky, Illinois, Maryland, New York, Utah, West Virginia, Wisconsin, and elsewhere. Smith

& Nephew's attempts to hide behind the veil of preemption have been rejected by numerous other Courts in cases involving the same BHR device. *Comella v. Smith & Nephew, Inc.*, 2013 WL 6504427 (N.D. Ill. 2013); *Elmore v. Smith & Nephew, Inc.*, 2013 WL 1707956 (N.D. Ill. 2013); *Gale v. Smith & Nephew, Inc.*, 989 F.Supp.2d 243 (S.D.N.Y. 2013); *Herron v. Smith & Nephew, Inc.*, 2014 WL 1232224 (E.D.Ca. 2014); *Tillman v. Smith & Nephew*, 2013 WL 3776973 (N.D.Ill. 2013); *Laverty v. Smith & Nephew, Inc.*, 1:15-cv-09485 (N.D. Ill. 2015); *Frederick v. Smith & Nephew, Inc.*, 2013 WL 6275644 (N.D. Ohio 2013); *Williams v. Smith & Nephew, Inc.*, 2015 U.S. Dist. LEXIS 108670 (D. Md. Aug. 18, 2015); *Raab v. Smith & Nephew, Inc.*, 14-CV-30279 (S.D.W.V., Dec. 15, 2015); and *Marion v. Smith & Nephew, Inc.*, 2016 U.S. Dist. LEXIS 99449.

GENERAL CLAIMS FOR RELIEF

38. This is a strict products liability and negligence action arising out of Defendant Smith & Nephew's violations of the Federal Code of Regulations, the State Laws of Alabama and the damages that Plaintiff Roy D. Cleveland suffered as a result of a defective hip implant.

39. Defendant, Smith & Nephew, Inc., is a developer and manufacturer of joint replacement systems. Since 2006, Defendant, Swmith & Nephew, Inc., has manufactured, introduced and/or delivered the Birmingham Hip Resurfacing System (hereinafter "BHR") into the stream of interstate commerce. The BHR is a metal-on-metal hip resurfacing prosthesis. It is comprised of the following two (2) components:

a. Birmingham Resurfacing Femoral Head; and

b. Birmingham Hip Resurfacing Acetabular Cup.

40. Before commercially distributing the BHR in the United States, federal law required Defendant, Smith & Nephew to submit an application for premarket approval ("PMA") of the device to the Secretary of Health and Human Services. On May 9, 2006, the Food and Drug

Administration ("FDA") completed its review of Defendant, Smith & Nephew's PMA application for the BHR. Based on the materials submitted by Defendant, Smith & Nephew, the FDA conditionally approved the BHR for commercial distribution.

41. The Approval Order from the FDA stated that "[c]ommercial distribution of a device that is not in compliance with these conditions is a violation of the [Food, Drug and Cosmetic] act, [21 U.S.C. §§301, et seq.]."

42. The Approval Order required Smith & Nephew to, among other things:

a. Submit a PMA supplement "when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing or device modification";

b. Submit an "'Adverse Reaction Report' or 'Device Defect Report' within 10 days after [Smith & Nephew] receives or has knowledge of information concerning…Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and…has been addressed by the device's labeling but is occurring with unexpected severity or frequency";

c. "[R]eport to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer…would be likely to cause or

contribute to a death or serious injury if the malfunction were to recur."

43. Additionally, the Approval Order cited many agreements Smith & Nephew made with the FDA, which became part of the approval. Thus, the Approval Order became an outline of the specific post-market obligations and duties Smith & Nephew undertook, in addition to all those existing under Federal Law, when it finally convinced the FDA to conditionally approve the BHR. Those agreements included, but were not limited to, the following:

a. Smith & Nephew would conduct a post-approval study and submit its reports biannually the first two years and annually for the next eight years following premarket approval, which study was to evaluate the "longer-term safety and effectiveness" of the BHR;

b. Smith & Nephew would implement a training program of its physicians, which was to include quarterly investigator teleconferences or meeting the first two years "to discuss study issues including adverse events; and to identify recommendations for improvement of the training program or labeling";

c. Smith & Nephew would "provide an analysis of adverse events and complaints (including MDRs) received regarding the BHR system";

d. Smith & Nephew would advise of the results of its post-approval studies, training program assessment, and adverse event analysis through a supplement in its labeling upon completion of the post-approval study, or at "earlier timepoints, as needed."

44. The Approval Order made clear that each requirement imposed upon Smith &

Nephew with respect to its distribution of the BHR system was to "ensure the safe and effective use of the device."

45. After Smith & Nephew received approval of the BHR system on May 9, 2006, but prior to Plaintiff's first resurfacing surgery in January 2011, Smith & Nephew became aware of defects in the BHR and harm it was causing, as well as deficiencies in surgeon training, but did not respond in accordance with its obligations, including but not limited to, the following:

a. Smith & Nephew received hundreds of adverse reports and complaints regarding the BHR but delayed its reporting to the FDA, and when it did communicate adverse reports, it did not do so properly but, in fact, attempted to blame others for the adverse events;

b. Smith & Nephew only initiated follow up inquiry on a fraction of adverse event reports by the patients' surgeons and sales force regarding the BHR;

c. Smith & Nephew became aware of wide evidence that the BHR systems were wearing down more quickly and severely than anticipated, and failed to take appropriate action to determine the cause and provide a solution, nor did it appropriately advise the FDA;

d. Smith & Nephew, when it did provide reports to the FDA pursuant to the Approval Order, underreported to and withheld information from the FDA about the likelihood of failure;

e. Smith & Nephew also failed to timely supplement its labeling as required in the Approval Order with information pertaining to the various failures of the BHR system, thereby misrepresenting the efficacy and safety of the BHR resurfacing products and actively misleading the FDA, the medical

community, patients, and public at large into believing that the BHR system was safe and effective.

46. Smith & Nephew's failures to follow the requirements of the Approval Order constitute violations of the Federal Food, Drug, and Cosmetic Act, pursuant to 21 CFR 801.109 and furthermore voids any legal protection that Defendant enjoys from tort claims as part of the device's PMA status.

FRAUDULENT CONCEALMENT

47. Smith & Nephew fraudulently concealed the fact that they did not enjoy legal protection provided as part of device's PMA status. Smith & Nephew failed to disclose information to the scientific and medical communities, as well as consumers, in violation of its duty to disclose. The information purposely withheld was material, and was information that consumers, such as Plaintiff could not have learned without Smith & Nephew's disclosure.

a. Specifically, Smith & Nephew intentionally withheld from consumers the fact that it no longer enjoyed PMA protection; at minimum, this material fact was intentionally withheld from the public, and consumers such as Plaintiff, until the formal recall in September 2015. Accordingly, consumers, such as Plaintiff, were misled into believing that they had no claim or recourse for the injuries suffered due to the BHR system.

b. Because Smith & Nephew intentionally withheld this material information concerning the PMA status, numerous Plaintiffs were harmed by relying on the nondisclosure, and acted on such reliance. Specifically, numerous Plaintiffs voluntarily dismissed active cases against Smith & Nephew because they were misled as to the BHR's PMA status.

c. Plaintiff Roy D. Cleveland Jr. is one such Plaintiff. His case was originally filed in Shelby County, Tennessee in the Thirtieth Judicial District at Memphis and was voluntarily

dismissed without prejudice pursuant to Order dated February 23, 2016. Because Plaintiff was harmed by Smith & Nephew's fraudulent concealment, Plaintiff is re-filing his Complaint within one year of the date of Order of Voluntary Non-Suit Without Prejudice, and well-within the statute of limitations based upon Smith & Nephew's fraudulent concealment.

PLAINTIFF'S INJURIES

48. On or about January 31, 2011**,** Plaintiff, Roy D. Cleveland, was admitted to St. Vincent Hospital in Birmingham, Alabama, for the purpose of undergoing a left hip resurfacing by Dr. Jeffrey C. Davis, who utilized and implanted the Defendant's Birmingham Hip Resurfacing system. Specifically, the following components of said system were utilized:

a. Smith and Nephew Birmingham Resurfacing Femoral Head 42 mm; and

b. Smith and Nephew Birmingham Hip Resurfacing Acetabular Cup 48 mm.

49. On or about February 18, 2013, Plaintiff underwent revision of his left hip due to left hip pain and other complications caused by the failure of the Defendant's Birmingham Hip Resurfacing system. Plaintiff's revision surgery was performed by Dr. Jeffrey C. Davis, at St. Vincent Hospital in Birmingham, Alabama. In his operative note, Dr. Davis describes metal debris and dark-stained tissue in Plaintiff's hip joint as a result of the premature failure of the device.

50. At the time of the initial resurfacing procedure in 2011, neither Plaintiff nor his surgeon were aware of the myriad of problems associated with the BHR. In fact, as stated below in more detail, Smith & Nephew continued to promote the BHR as a safe alternative to other metal-on-metal hip devices in 2015, and did not withdraw the device from the U.S. market until after Plaintiff's revision surgery.

FIRST CLAIM FOR RELIEF

STRICT PRODUCTS LIABILITY BASED ON VIOLATIONS OF 21 C.F.R. 820.30 (f) and (g); 21 C.F.R. 820.80 (c) and (d); 21 C.F.R. 820.100; 21 C.F.R. 820.198

Plaintiff herein incorporates, reasserts and re-alleges the allegations set forth above in paragraphs 1-50 by reference as if fully set forth herein below.

51. Defendant designed and/or manufactured the BHR Systems implanted in Plaintiff's left hip, in violation of the Federal Food, Drug and Cosmetic Act ("Act") and regulations promulgated pursuant to it, as well as the duties created by virtue of the agreements in the Approval Order.

52. At the time the BHR Systems, including the Acetabular Cups and Femoral Heads, left the control of Defendant, Smith & Nephew, they were unreasonably dangerous due to Defendant's non-compliance with the Act, and the regulations promulgated pursuant to it and the Approval Order in one or more of the following ways:

a. Failed to accurately establish the in vivo life expectancy of the BHR, in violation of 21 C.F.R. 820.30(f);

b. Failed to validate the anticipated wear of the acetabular cup prior to its release into commercial distribution, in violation of 21 C.F.R. 820.30(g);

c. Failed to establish and maintain appropriate reliability assurance testing to validate the BHR design both before and after its entry into the marketplace, in violation of 21 C.F.R. 820.30 (g);

d. Failed to conduct adequate bio-compatibility studies to determine the BHR's latent propensity to effuse metallic contaminants into the human blood and tissue;

e. Failed to identify the component discrepancy, in violation of 21 C.F.R. 820.80(c);

f. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. 820.80(d);

g. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints regarding the BHR, returned BHR, and other quality problems associated with the BHR, in violation of 21 C.F.R. 820.100;

h. Failed to appropriately respond to adverse incident reports and complaints that strongly indicated the acetabular component was Malfunctioning [as defined in 21 C.F.R. 803.3], or otherwise not responding to its Design Objective Intent, in violation of 21 C.F.R. 820.198;

i. Failed to conduct complete device investigations on returned BHR and components, including the acetabular component, in violation of 21 C.F.R. 820.198; and/or

j. Continued to place the BHR into the stream of interstate commerce when it knew, or should have known, that the acetabular component was Malfunctioning [as defined in 21 C.F.R. 803.3] or otherwise not responding to its Design Objective Intent.

k. Failed to investigate reports of User Error so as to determine why User Error was occurring and to try to eliminate User Error in the future through improved physician training.

53. Smith & Nephew's failure to comply with the above-stated requirements is evident through the following non-exhaustive list of malfeasance, misfeasance, and/or nonfeasance on the part of Defendant:

a. Smith & Nephew allowed and encouraged its commission-based salesmen to not report adverse events and complaints such as revision surgeries, thereby substantially reducing the known and reported incidence of product problems;

b. Smith & Nephew willfully ignored the existence of numerous adverse events and complaints, such as revision surgeries, which it knew or should have known were not being reported to the company or the FDA;

c. Smith & Nephew received hundreds of adverse reports regarding the BHR system but delayed its reporting to the FDA;

d. Smith & Nephew failed to properly communicate adverse events to the FDA, when it did report them, and when doing so, wrongly attempted to blame others for the adverse events;

e. Smith & Nephew also failed to analyze the adverse events and revision surgeries of which it was aware to determine why so many revisions were required so soon after implantation;

f. Smith & Nephew failed to investigate and report on "unanticipated events," i.e., any adverse event not listed on the label;

g. Smith & Nephew failed to investigate all Device Failures;

h. Smith & Nephew failed to revise its instructions to doctors and its surgical techniques documents to reflect the true problematic experience with the BHR;

i. Smith & Nephew also knew but failed to disclose that some of the surgeons – both overseas and domestically - upon whose data it relied to boast a high success rate for the BHR had been bribed or paid financial kickbacks or illegal payments and remuneration in order to use the BHR;

j. Smith & Nephew willfully ignored the existence of numerous complaints about failures associated with components of the BHR that were being used in illegal combinations throughout the United States when, in fact, those revision surgeries should have been thoroughly investigated because such usage constitutes an unlawful design change and would

provide insight into possible problems that may not be readily seen when the BHR system was used as a completed, unaltered system;

k. Smith & Nephew, as a result of increased demand for the product, failed to properly train all surgeons and Original Core Surgeons using the product as required by the Approval Order by using shortcuts, such as teaching surgeons by satellite instead of hands on as it had assured the FDA and by failing to require those surgeons to receive such training directly from the product designers in the United Kingdom or from Original Core Surgeons;

l. Smith & Nephew also misrepresented to the surgeons in the United States that in vivo testing of the BHR had been undertaken when Defendant, in fact, knew or should have known that the testing was invalid and the results unreliable.

m. Smith & Nephew failed to timely supplement its labeling as required in the Approval Order with information pertaining to the various failures of the BHR system, thereby misrepresenting the efficacy and safety of the BHR resurfacing products to the FDA and actively misleading the FDA, the medical community, patients, and public at large into believing that the BHR system was safe and effective when it was not by, among other things, claiming to have solved the problem of metal-on-metal friction due to a "fluid film" theory that has proven untrue.

54. As a direct and proximate result of Defendant's violations of one or more of these federal statutory and regulatory standards of care, a BHR System, including the acetabular cup and

femoral head, was implanted in Plaintiff's left hip, and failed and such failure directly and proximately caused and/or contributed to the severe and permanent injuries the Plaintiff sustained and endured as defined in 21 C.F.R. 803.3. As a direct and proximate result, Plaintiff, endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

55. This cause of action is based entirely on the contention that Defendant, Smith & Nephew violated federal safety statutes and regulations, as well as the conditions established in the Approval Order with which Defendant agreed to comply to obtain premarket approval of the device. Plaintiff does not bring the underlying action as an implied statutory cause of action, but rather he is pursuing parallel state law claims based upon Defendant, Smith & Nephew's violations of the applicable federal regulations and Approval Order.

56. Under Alabama law, Defendant, Smith & Nephew's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of strict liability in tort.

57. Thus, under Alabama law, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, and there is no need for the Alabama Legislature to act in order to create such a remedy.

58. The Act contains an express preemption provision, 21 U.S.C. §360(k), which in relevant part states: "no state or political subdivision of a state may establish or continue in effect

with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§301, et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§301, et seq.]."

59. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. §306(k) because the violations alleged are all based on an exclusively federal statutory and regulatory set of requirements and express agreements with the FDA which include no "requirement which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder. *See; Bausch v. Stryker*, 630 F.3d 546, 556 (7th Cir. 2010) (claims for negligence and strict products liability relating to a Class III medical device were not expressly preempted by federal law to the extent they were based on the defendants' violations of federal law). As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder.

60. As a direct and proximate result of Defendant Smith & Nephew's aforementioned actions, Plaintiff prays for judgment against Defendant, Smith & Nephew, Inc., in an amount in excess of Seventy Five Thousand Dollars ($75,000.00).

SECOND CLAIM FOR RELIEF

NEGLIGENCE BASED ON VIOLATIONS OF 21 C.F.R. 820.30 (f) and (g); 21 C.F.R. 820.80 (c) and (d); 21 C.F.R. 820.100; 21 C.F.R. 820.198

Plaintiff herein incorporates, reasserts and re-alleges the allegations set forth above in paragraphs 1-60 by reference as if fully set forth herein below.

61. The BHR Systems, including the acetabular cups and femoral heads, implanted in Plaintiff's left hip on January 31, 2011 were designed and/or manufactured in violation of the Act and regulations promulgated to it.

62. It was the duty of Defendant, Smith & Nephew, Inc. to comply with the Act, and the regulations promulgated pursuant to it, as well as the conditions established in the Approval Order with which Defendant agreed to comply in order to obtain premarket approval of its device. Yet, notwithstanding this duty, Defendant, Smith & Nephew, Inc. violated the Act in one or more of the following ways:

a. Failed to accurately establish the in vivo life expectancy of the BHR, in violation of 21 C.F.R. 820.30(f);

b. Failed to validate the anticipated wear of the acetabular cup prior to its release into commercial distribution, in violation of 21 C.F.R. 820.30(g);

c. Failed to establish and maintain appropriate reliability assurance testing to validate the BHR design both before and after its entry into the marketplace, in violation of 21 C.F.R. 820.30 (g);

d. Failed to conduct adequate bio-compatibility studies to determine the BHR's latent propensity to effuse metallic contaminants into the human blood and tissue;

e. Failed to identify the component discrepancy, in violation of 21 C.F.R. 820.80(c);

f. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. 820.80(d);

g. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints regarding the BHR, returned BHR, and other quality problems associated with the BHR, in violation of 21 C.F.R. 820.100;

h. Failed to appropriately respond to adverse incident reports and complaints that strongly indicated the acetabular component was Malfunctioning [as defined in 21 C.F.R. 803.3], or otherwise not responding to its Design Objective Intent, in violation of 21 C.F.R. 820.198;

i. Failed to conduct complete device investigations on returned BHR and components, including the acetabular component, in violation of 21 C.F.R. 820.198; and/or

j. Continued to inject BHR into the stream of interstate commerce when it knew, or should have known, that the acetabular component was Malfunctioning [as defined in 21 C.F.R. 803.3] or otherwise not responding to its Design Objective Intent.

k. Failed to investigate reports of User Error so as to determine why User Error was occurring and to try to eliminate User Error in the future through improved physician training.

61. Smith & Nephew's failure to comply with the above-stated duties is evident through the following non-exhaustive list of malfeasance, misfeasance, and/or nonfeasance on the part of Defendant:

a. Smith & Nephew allowed and encouraged its commission-based salesman to not report adverse events and complaints such as revision surgeries, thereby substantially reducing the known and reported incidence of product problems;

b. Smith & Nephew willfully ignored the existence of numerous adverse events and complaints, such as revisions surgeries, which it knew or should have known were not being reported to the company or the FDA;

c. Smith & Nephew received hundreds of adverse reports regarding the BHR system but delayed reporting them to the FDA without any justification or excuse for such delays;

d. Smith & Nephew failed to properly communicate adverse events to the FDA, when it did, in fact, report them, and when doing so, wrongly attempted to blame others for the adverse events;

e. Smith & Nephew also failed to analyze the adverse events and

revision surgeries of which it was aware to determine why so many revisions were required so soon after implantation;

f. Smith & Nephew failed to investigate and report on "unanticipated events," i.e., any adverse event not listed on the label;

g. Smith & Nephew failed to investigate all Device Failures;

h. Smith & Nephew failed to revise its instructions to doctors and its surgical techniques documents to reflect the true experience with the BHR;

i. Smith & Nephew also knew but failed to disclose that some of the surgeons –both overseas and domestically - upon whose data it relied to boast a high success rate for the BHR had been bribed or paid financial kickbacks or illegal payments and remuneration in order to use the BHR;

j. Smith & Nephew willfully ignored the existence of numerous complaints about failures associated with components of the BHR that were being used in illegal combinations throughout the United States when, in fact, those revision surgeries should have been thoroughly investigated because such usage constitutes an unlawful design change and User Error and would provide insight into possible problems that may not be readily seen when the BHR system was used as a completed, unaltered system;

k. Smith & Nephew, as a result of increased demand for the product, failed to properly train all surgeons and Original Core Surgeons using the product as_required by the Approval Order by using shortcuts, such as teaching surgeons by satellite instead of hands on as it had assured the FDA and by failing to require those surgeons to receive such training directly

from the product designers in the United Kingdom or from Original Core Surgeons;

l. Smith & Nephew also misrepresented to the surgeons in the United States that in vivo testing of the BHR had been undertaken when Defendant, in fact, knew or should have known that the testing was invalid and the results unreliable;

m. Smith & Nephew failed to timely supplement its labeling as required in the Approval Order with information pertaining to the various failures of the BHR system, thereby misrepresenting the efficacy and safety of the BHR resurfacing products to the FDA and actively misleading the FDA, the medical community, patients, and public at large into believing that the BHR system was safe and effective when it was not by, among other things, claiming to have solved the problem of metal-on-metal friction due to a "fluid film" theory that has proven untrue.

63. As a direct and proximate result of Defendant, Smith and Nephew's violations of one or more of these federal statutory and regulatory standards of care, and the Approval Order, a BHR System, including the acetabular cup and femoral head, was implanted in Plaintiff's left hip on January 31, 2011 and failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff, as defined in 21 C.F.R. 803.3. As a direct and proximate result, Plaintiff endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering,

inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

64. This cause of action is based entirely on the contention that Defendant, Smith & Nephew violated federal safety statutes and regulations. Plaintiff does not bring the underlying action as an implied statutory cause of action, but rather he is pursuing parallel state common law claims based upon Defendant, Smith & Nephew's violations of the applicable federal regulations.

65. Under Alabama law, Defendant, Smith & Nephew's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of negligence.

66. Thus, under Alabama law, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, and there is no need for the Alabama Legislature to act in order to create such a remedy.

67. The Act contains an express preemption provision, 21 U.S.C. §360(k), which in relevant part states: "no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§301, et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§301, et seq.]."

68. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. §306(k) because the violations alleged are all based on an exclusively federal statutory and regulatory set of requirements which include no "requirement which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder. *See; Bausch v. Stryker*, 630 F.3d 546, 556 (7th Cir. 2010) (claims for negligence and strict products

liability relating to a Class III medical device were not expressly preempted by federal law to the extent they were based on the defendants' violations of federal law). As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder.

69. As a direct and proximate result of Defendant, Smith & Nephew's aforementioned actions, Plaintiff Roy D. Cleveland Jr. prays for judgment against Defendant, Smith & Nephew, Inc. in an amount in excess of Seventy Five Thousand Dollars ($75,000.00).

THIRD CLAIM FOR RELIEF
(Breach of Express Warranties)

70. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

71. The Defendant warranted, both expressly and impliedly, through its marketing, advertising, distributors and sales representatives, that the BHR resurfacing products were of merchantable quality, fit for the ordinary purposes and uses for which it was sold.

72. Defendant expressly warranted to Plaintiff, by and through Defendant and/or its authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that the system was safe, effective, fit and proper for its intended use.

73. The Defendant is aware that health care providers and patients, including the Plaintiff, rely upon the representations made by the Defendant when choosing, selecting and purchasing its products, including the BHR resurfacing products.

74. Due to the defective and unreasonably dangerous BHR resurfacing products, it was neither of merchantable quality nor fit for the particular purposes for which it was sold, presenting an unreasonable risk of injury to patients, including Plaintiff, during foreseeable use.

75. Defendant breached their warranty of the mechanical soundness of the BHR system

by continuing sales and marketing campaigns highlighting the safety and efficacy of its product, while Defendant knew or should have known of the defects and risk of product failure and resulting patient injuries.

76. Defendant made numerous claims to the general public, and to Plaintiff in particular, that the BHR devices were safe for their intended use and that they did not suffer from the same problems that plague other metal-on-metal hips, even though it was in possession of information to the contrary. For example, almost one year before Plaintiff's initial surgery, Defendant's senior vice president publicly touted the BHR as being "unlike any other metal-on-metal hip implant" with a survivorship rate superior to even traditional non-metal devices due to its "distinctive metallurgy heritage" and other factors.[12]

77. As recently as January, 2015, Defendant referred patients with questions about the BHR devices to a website, www.surfacehippy.com, with claims about people with the BHR devices who completed extraordinary physical feats after implantation, including a "sprint triathlon" with their prosthetic BHR devices.[13]

78. Pursuant to 21 U.S.C. §360k, the above statements constitute a violation of the PMA because the FDA's conditional approval of the BHR devices warned Defendant that its "warranty statements must be truthful, accurate, and not misleading, and must be consistent with

[12] Smith & Nephew, Press Release, *New Clinical Results Further Distance the BIRMINGHAM HIP Resurfacing System from Failed Metal-on-Metal Hip Implants*, February 9, 2012. Smith & Nephew published similar press releases on its Web site on Dec. 7, 2007, and again on May 4, 2010.

[13] See Patricia Walter, *MPH's Hip Resurfacing with Mr. Shimmin*, available at http://www.surfacehippy.info/hipresurfacing/hip-stories/additional-stories/760-mph-s-hip-resurfacing-with-mr-shimmin-2015 (describing a BHR recipient who completed a triathlon in December 2014, exactly 11 months after being implanted with a BHR); the website has been promoted to Smith & Nephew patients by company executives, including but not limited to Tunja Carter, Senior Clinical Affairs Specialist.

applicable Federal and State Laws."

79. The defective and unreasonably dangerous condition of the BHR products constituted a breach of the Defendant's express warranties under Alabama law.

80. The above-mentioned violations and failures constitute a parallel violation of Alabama common law and statutory law that predates and operates independently from the above federal requirements.

81. As a direct and proximate result of Defendant's breaches of express warranties, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint, including metallosis, tissue damage and necrosis, revision surgery, exposure to toxic levels of chromium and cobalt ions in his body, and unknown long-term consequences that continue to this day and into the future. He has further suffered past and future medical expenses, past and future wage loss; physical pain and suffering, both past and future; mental anguish and emotional distress.

FOURTH CLAIM FOR RELIEF
(Breach of Implied Warranties)

82. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

83. Defendant impliedly warranted that the BHR system was merchantable and was fit for the particular purposes for which they were intended.

84. Defendant had reason to know the particular purpose for which its BHR products were required, and that Plaintiff was relying on Defendant's skill and judgment to furnish suitable goods. For example, the PMA Letter approving the BHR device noted that it is particularly well suited for younger or more active patients who "may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral hip joint revision."

85. When the BHR products were implanted in Plaintiff to treat his damaged and worn hip joints, the BHR products were being used for the particular purposes for which they were intended, and they were particularly intended for Plaintiff because he was only 60 years old at the time of implantation in 2011.

86. Plaintiff, individually and/or by and through his healthcare provider, relied upon Defendant's implied warranties of merchantability and fitness for a particular purpose, in consenting to have the BHR products implanted, with the hope and expectation that the metal-on-metal device would last longer than a traditional polyethylene or ceramic prosthetic device and thus not require a painful revision surgery.

87. Defendant breached these implied warranties of merchantability and fitness for a particular purpose because the BHR products implanted in Plaintiff were neither merchantable nor suited for the intended uses as warranted, because they carried a high risk of premature failure due to metallosis.

88. Defendant's breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of Plaintiff, placing Plaintiff's health and safety in jeopardy.

89. The above-mentioned violations and failures constitute a parallel violation of Alabama common law and statutory law that predates and operates independently from the above federal requirements.

90. As a direct and proximate result of Defendant's breaches of these implied warranties, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint, including metallosis, tissue damage and necrosis, revision surgery, exposure to toxic levels of chromium and cobalt ions in his body, and unknown long-term consequences that

continue to this day and into the future. He has further suffered past and future medical expenses, past and future wage loss; physical pain and suffering, both past and future; mental anguish and emotional distress.

FIFTH CLAIM FOR RELIEF
(Negligent Misrepresentation)

91. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

92. Defendant had a duty to accurately and truthfully represent to the medical community, Plaintiff, and the public that BHR products had not been adequately tested and found to be safe and effective for the treatment of damaged and worn parts of the hip joint. Instead, the representations made by Defendant were false.

93. Defendant negligently misrepresented to the medical community, Plaintiff, and the public that the BHR products did not have a high risk of dangerous adverse side effects. Defendant made this misrepresentation by consistently underreporting adverse events for the BHR, delaying reporting of adverse events, and categorizing them in a way that hid the true risk of failure due to metal-on-metal symptoms, in violation of the terms of the PMA and 21 C.F.R. 822.2 and 21 C.F.R. 814.82 to 814.84.

94. Had Defendant accurately and truthfully represented to the medical community, Plaintiff, and the public the material facts relating to the risks of the BHR products, Plaintiff and/or Plaintiff's healthcare providers would not have utilized Defendant's BHR products for Plaintiff's treatment.

95. Defendant effectively deceived and misled the scientific and medical communities and consumers regarding the risks and benefits of the BHR system. Defendant did not inform the

public or Plaintiff until, at the earliest, June 2015, when Defendant attempted to pull the product from the market for certain populations, including all women.

96. The above-mentioned violations and failures constitute a parallel violation of Alabama common law that predates and operates independently from the above federal requirements.

97. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint, including metallosis, tissue damage and necrosis, revision surgery, exposure to toxic levels of chromium and cobalt ions in his body, and unknown long-term consequences that continue to this day and into the future. He has further suffered past and future medical expenses, past and future wage loss; physical pain and suffering, both past and future; mental anguish and emotional distress.

SIXTH CLAIM FOR RELIEF
(Unfair and Deceptive Trade Practices)

98. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

99. Plaintiff purchased and used Defendant's BHR resurfacing products primarily for personal use and thereby suffered ascertainable losses as a result of Defendant's violations of the PMA Letter and various federal regulations governing the BHR device, which also constitute parallel violations of Alabama's consumer protection laws, specifically the Alabama Deceptive Trade Practices Act ("ADTPA"). In particular, Defendant's failure to report adverse events in a timely manner, and its failure to adequately disclose the high risk of premature failure of the BHR device, as described in more detail above, constitutes a violation of federal law and FDA regulations.

100. Had Defendant not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Defendant's BHR resurfacing products, and would not have incurred related medical costs and injuries.

101. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, monies from Plaintiff for the BHR resurfacing products that would not have been paid had Defendant not engaged in unfair and deceptive conduct.

102. Defendant's actions, as complained of herein, and as suppliers, manufacturers, advertisers, and sellers, constitute unfair, unconscionable, deceptive, and/or fraudulent acts or trade practices, which also constitutes a parallel violation of the ADTPA, Ala. Code § 8-19-1, et. seq.

103. As a direct and proximate result of Defendant's unfair and deceptive trade practices, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint, including metallosis, tissue damage and necrosis, revision surgery, exposure to toxic levels of chromium and cobalt ions in his body, and unknown long-term consequences that continue to this day and into the future. He has further suffered past and future medical expenses, past and future wage loss; physical pain and suffering, both past and future; mental anguish and emotional distress.

SEVENTH CLAIM FOR RELIEF
(Fraudulent Concealment)

104. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

105. Throughout the relevant time period, Defendant knew that its BHR resurfacing products were defective and unreasonably unsafe for their intended purpose.

106. Defendant was under a duty to disclose to Plaintiff and the medical community the defective nature of the BHR resurfacing products because Defendant was in a superior position to

know the true quality, safety, and efficacy of the BHR resurfacing products. Defendant fraudulently concealed the danger of the BHR device by underreporting adverse events for the BHR, delaying reporting of adverse events, and categorizing them in a way that hid the true risk of failure due to metal-on-metal symptoms, in violation of the terms of the PMA and 21 C.F.R. §822.2 and 21 C.F.R. §§814.82 - 814.84.

107. Defendant fraudulently concealed from and/or failed to disclose to Plaintiff, Plaintiff's healthcare providers, and the medical community that its BHR resurfacing products were defective, unsafe, and unfit for the purposes intended, and that they were not of merchantable quality.

108. The facts concealed and/or not disclosed to Plaintiff and the medical community were material facts that a reasonable person would have considered important in deciding whether to utilize Defendant's BHR resurfacing products.

109. Defendant's fraudulent concealment, as complained of herein, constitutes a parallel violation of Alabama common law that predates and operates independently from the above federal requirements.

110. As a direct and proximate result of Defendant's fraudulent concealment, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint, including metallosis, tissue damage and necrosis, revision surgery, exposure to toxic levels of chromium and cobalt ions in his body, and unknown long-term consequences that continue to this day and into the future. He has further suffered past and future medical expenses, past and future wage loss; physical pain and suffering, both past and future; mental anguish and emotional distress.

EIGHTH CLAIM FOR RELIEF
(Negligent Infliction of Emotional Distress)

111. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

112. Defendant carelessly and negligently manufactured, developed, tested, labeled, marketed, and sold the BHR products to Plaintiff, carelessly and negligently concealing the harmful effects from Plaintiff, and carelessly and negligently misrepresented the quality, safety, and efficacy of the products, in violation of the terms of its PMA Letter and federal regulations, as described in greater detail above.

113. Plaintiff was directly impacted by Defendant's carelessness and negligence in that Plaintiff purchased the BHR products and has therefore sustained and will continue to sustain emotional distress, physical injuries, economic losses, and other damages.

114. Defendant's actions, as complained of herein, negligently inflicted emotional distress upon the Plaintiff. The above-mentioned violations and failures and failures to comply with federal regulations constitute a parallel violation of Alabama common law that predates and operates independently from the above federal requirements. Alabama common law furthermore allows this cause of action on Plaintiff's behalf because the BHR device came into contact with his body, and his injuries were severe.

115. As a direct and proximate result of Defendant's negligent infliction of emotional distress, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint, including metallosis, tissue damage and necrosis, revision surgery, exposure to toxic levels of chromium and cobalt ions in his body, and unknown long-term consequences that continue to this day and into the future. He has further suffered past and future medical expenses, past and future wage loss; physical pain and suffering, both past and future; mental anguish and emotional distress.

NINTH CLAIM FOR RELIEF
(Punitive Damages)

116. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

117. The acts and omissions of the Defendant as set forth herein constitute intentional, fraudulent, malicious and/or reckless conduct. Accordingly, Plaintiff is entitled to an award of punitive damages.

WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray that this Court enter judgment against the Defendant in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), together with pre-judgment and post judgment interest, attorneys' fees and costs of this action as may be recoverable, and for such further relief as this Court deems just and reasonable.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dated this 13th day of February, 2017.

REEVES & MESTAYER

Original signature on file at Reeves & Mestayer

s/James R. Reeves, Jr.
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